

§ 123.5

21 CFR Ch. I (4-1-04 Edition)

(h) *Molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) *Preventive measure* means physical, chemical, or other factors that can be used to control an identified food safety hazard.

(j) *Process-monitoring instrument* means an instrument or device used to indicate conditions during processing at a critical control point.

(k)(1) *Processing* means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(2) The regulations in this part do not apply to:

(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.

(ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.

(iii) The operation of a retail establishment.

(l) *Processor* means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) *Scombroid toxin-forming species* means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

(n) *Shall* is used to state mandatory requirements.

(o) *Shellfish control authority* means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of

molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) *Shellstock* means raw, in-shell molluscan shellfish.

(q) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(r) *Shucked shellfish* means molluscan shellfish that have one or both shells removed.

(s) *Smoked or smoke-flavored fishery products* means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

§ 123.5 Current good manufacturing practice.

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

§ 123.6 Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plan.

(a) *Hazard analysis.* Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably

likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b) *The HACCP plan.* Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

- (i) Natural toxins;
- (ii) Microbiological contamination;
- (iii) Chemical contamination;
- (iv) Pesticides;
- (v) Drug residues;

(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor rep-

resents, labels, or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives; and

(ix) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and

(ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with §123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with §123.8(a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification of the plan in accordance with §123.8(a)(1).

(e) *Products subject to other regulations.* For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the

§ 123.7

HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

(f) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §123.11(b) they need not be included in the HACCP plan, and vice versa.

(g) *Legal basis.* Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

§ 123.7 Corrective actions.

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with §123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not

21 CFR Ch. I (4-1-04 Edition)

have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with §123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with §123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with §123.8(a)(3)(ii) and the record-keeping requirements of §123.9.

§ 123.8 Verification.

(a) *Overall verification.* Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1) *Reassessment of the HACCP plan.* A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended